The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME response to the EDQM request for comments on a Draft Council of Europe Guidance Document on Traceability of Medicines in Hospital Settings

On 25 April 2024, the CPME Board adopted the 'EDQM request for comments on a Draft Council of EuropeGuidance Document on Traceability of Medicines in Hospital Settings' (CPME 2024/083).

Annex I: draft response to the consultation
Annex II: draft Council of Europe Guidance Document on Traceability of Medicines in Hospital

Annex I

(***** This question is mandatory)

*** 1. From which sector are you responding?** Choose one of the following answers

Internationalorganisation
National Competent Authority / Regulator Patient or Patient Safety Association
PharmacistAssociation
X Medical Profession Association
Industry Association
Other (please specify)

*** 2. What type of interested party do you represent?**

Choose one of the following answers
X European interested parties
National interested parties

*** 3. What is the name of your organisation?**

Standing Committee of European Doctors (CPME)

*** 4. Contact information (email address)**

diogo.teixeira.pereira@cpme.eu

*** 5. Do you think that the document addresses the issue of Traceability of Medicines in Hospital Settings in a comprehensive way?**

Choose one of the following answers
X Yes

No
Unsure
If No or Unsure, please explain:
-

*** 6. Do you think that the document is clear?**
Choose one of the following answers
X Yes
No
Unsure

If No or Unsure, please explain:
-

*** 7. Do you think that the document is adapted for potential future developments in terms of the digitalisation of healthcare processes?**
Choose one of the following answers
X Yes
No
Unsure

If No or Unsure, please explain:

*** 8. Do you think that the document presents any issues in terms of conflicting requirements with existing national guidance and/or legislation?**
Choose one of the following answers
Yes
X No
Unsure

If No or Unsure, please explain:
-

*** 9. Do you think that the document is missing any elements of practice from your own area (e.g. national competent authority and regulator, hospital, industry)?**
Choose one of the following answers
Yes
X No
Unsure

If No or Unsure, please explain:
-

*** 10. Do you think that the document provides sufficient guidance for its implementation by all interested parties (policy-makers and regulators, industry, hospital boards, hospital IT managers and service providers, hospital quality management departments, hospital pharmacists, other healthcare professionals in the hospital such as physicians and nurses, healthcare payments bodies such as NHS or insurance companies, patients)?**
Choose one of the following answers
X Yes

No
Unsure
If No or Unsure, please explain:
If you have any comments on specific parts of the document, please use the following sections.

Use the given tables and put a clear reference and line number you are commenting on, and, if applicable, make concrete suggestions for alternative wording.

17. Section 7 - Processes

	Lines concerned by comment	Comment type – Editorial/Technical/Other	Comment on the text (enter comment)	Suggested text (enter text)
Comment 1	547	Editorial	Doctors have the authority to prescribe medications, possess clinical expertise to ensure appropriate usage, advocate for patient's health and collaborate with healthcare teams. Consequently, doctors should also be included as ambassadors of safe medication errors together with hospital pharmacists.	Hospital pharmacists and Doctors.

27. Section 17 – Definitions

	Lines concerned by comment	Comment type – Editorial/Technical/Other	Comment on text (enter comment)	Suggested text (enter text)
Comment 1	282-283	Editorial	It is important to underline, following the	Any mistake in ordering, prescribing,

			EMA definition of medication error, that a medication error lead or has the potential to lead to harm the patient.	dispensing, administering or monitoring (the effect of) a medication **that can lead or has the potential to lead to harm to the patient.**

Annex II: draft Council of Europe Guidance Document on Traceability of Medicines in Hospital Settings

Annex II

Traceability of Medicines in Hospital Settings

Background

The European Directorate for the Quality of Medicines & HealthCare (EDQM) is a Directorate of the Council of Europe, an intergovernmental organisation based in Strasbourg, France, set up to promote democracy and protect human rights and the rule of law in Europe. The EDQM is in charge of ensuring the basic human right of access to good quality medicines and healthcare in Europe.

This mission and the development of common policy instruments and legal standards is ensured through intergovernmental structures such as the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and its subordinate bodies, the Committee of Experts on Minimising Public Health Risks Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED) and the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC). These committees are composed of representatives from all the member states of the Council of Europe having acceded to the Partial Agreement on the European Pharmacopoeia (Ph. Eur. member states), and support these member states by anticipating and addressing challenges in their respective fields of expertise.

In September 2019, the CD-P-PH approved a project proposal to develop guidance on the traceability of medicines in hospitals. The project was included in the committee's Terms of Reference for 2020-21; however, work could not start immediately due to resource and prioritisation issues. Following the establishment of a working group, the drafting process started in 2022 as a joint initiative of the Committees of Experts CD-P-PH/PC and CD-P-PH/CMED to develop best practices for the traceability of medicines in hospital settings to minimise the incidence of medication administration errors and ensure patient safety.

The aim is to propose harmonised approaches to traceability practices in Ph. Eur. member states through a guidance document to be further disseminated and promoted by the EDQM and member states. Its implementation in the member states' regulations will need to be monitored and evaluated.

Acknowledgments (to be added to the next version)


DRAFT DOCUMENT

Traceability of Medicines in Hospital Settings

EDQM, Council of Europe

27 March 2024

1. Executive summary

Patient safety is an important and internationally recognised issue in healthcare. Safe medication processes are one of the drivers for improving patient safety. The medication process in healthcare institutions comprises multiple steps, all of which must be addressed to enhance medication safety. This document focuses on achieving full traceability of medicines in a hospital setting, which is key to improving medication safety. The overarching goal is clear, but important conditions and potential barriers affect the speed at which this goal can be achieved. The concept may seem simple, but the execution has proved complex. However, practices in some leading hospitals in Europe indicate that the principles of in-hospital medication traceability are applied. Sharing details of these cases and their outcome can facilitate the process in other hospitals and countries.

In a hospital setting, traceability of medicines benefits patient safety. Medication administration errors in a hospital will be minimised if individual units of a medicine can be traced back to the point of administration. This traceability consists of the seven "rights" of medication administration: right patient, right medicinal product, right dose, right time, right administration route, right information and right documentation. In the event of a recall, it is also easier to identify properly traced medicines and the patients who are at risk, preventing administration of recalled medicinal products.

Traceability is contingent on several conditions and process steps: traditionally, medication administered to a patient is checked against the prescription and is recorded in a section of the patient medical record. If paper files are used, these are manual procedures, and any check will be a manual check in the individual patient files. If this is the case, only the medication name, dosage and administration route will be recorded in the patient file. With manual medication administration registration, at peak times there are risks of missed recording. Audits are performed at the individual patient level, but in these circumstances these audits are manual, time-consuming and very limited in their ability to prevent errors. Manual recalls are time-consuming and may focus on containing potentially affected stock, as manual tracing of potentially affected patients would require reviewing many paper patient records. As manual procedures tend to be incomplete, it is obvious that they do not fully comply with and achieve the goal of traceability.

Procedures based on barcode scanning are standardised, faster and more secure. In addition, these procedures facilitate (fast and secure) registration of data/information and monitoring. Although barcode scanning may be omitted at hectic times, it supports a standardised way of working and is faster and safer. The scanned data contain more information than a manual record, and the information is recorded automatically, allowing for secure (and even automated) checks.

Information technology (IT), digitalisation and electronic documentation are increasingly finding their way into healthcare and in hospitals. Digitalisation facilitates traceability. Digitalisation also benefits from the standardisation of procedures (administrative, logistic and clinical), the use of IT standards, etc. Electronic documentation is clear and can be immediately available to all healthcare providers, reducing communication errors.

However, investments in IT are costly and hospital budgets limited. Healthcare systems vary from country to country, with governance falling into two main categories: public hospitals (under local/regional/national governance) and privately-owned hospitals in a more market-oriented economy. When it comes to promoting and supporting technological developments in healthcare, national regulation or government sponsorship may vary. The implementation of IT varies between hospitals – even within the same country. As hospitals are complex organisations with many processes supporting the care process, hospitals often require multiple IT systems on their journey to full digitalisation. Solution providers responsible for IT systems may vary, as few provide services both regionally and globally. (International) certification and accreditation enhances the visibility of IT status.

Digitalisation requires new ways of thinking and designing, 'new pathways', cultural changes, process changes and in fact – to be successful – major change management. It also brings a whole new group of professionals to the forefront of the hospital, IT experts who design the IT architecture, support the technology, maintain the new IT systems and support the clinical professionals. In addition, digitalisation also results in a major change for existing healthcare professionals, who should view digitalisation as a means to optimise care and use new technologies to facilitate their current workflow and thereby improve patient care. As a result of digitalisation, specific new roles have developed in hospitals (Chief Medical Information Officer (CMIO), Chief Pharmacy Informatics Officer (CPIO) and the Chief Nursing Information Officer (CNIO)).

Given the diversity of hospitals and available IT systems, it is impossible to write a 'blueprint' for in-hospital traceability that covers the topic for all countries in Europe. This document is intended to serve as a guide to understand the importance of the issue, share experiences and best practices, and encourage organisations to take the next step in improving traceability and patient safety.

2. Context

Medication is an important component in the treatment of diseases. The purpose of medication can be curative, preventive, alleviation of symptoms and self-treatment of ailments. In hospital care, the prescription and administration of medication by hospital staff are common practice and ideally the processes are well controlled. In recent years, the increased focus on patient safety has also meant that additional attention is being paid to medication errors. In 2007 the 'Preventing Medication Errors' report found that patient harm caused by medication errors is common, costly and, to a large extent, preventable. An intervention such as barcoded medication administration increases administration accuracy and supports medication traceability up to the patient, preventing harm and even unnecessary deaths.

Reducing medication errors is one strategy to enhance patient safety. In EU member states, the Falsified Medicines Directive (Directive 2011/62/EU, FMD) was implemented in 2019 to prevent the entry of falsified medicinal products into the healthcare supply chain. Preventing this entry has a positive effect on patient safety. However, in some hospitals, pharmacists still consider the implementation of the FMD as an additional administrative burden with limited added value for patient safety. As a result of this legislation, every unit of secondary packaging of prescription-only medicines in the EU has a unique barcode, allowing the pharmacy to check the legitimacy of the medication before dispensing. Each secondary package holds several individually packed medicines (units). However, the FMD does not provide for barcoding at the primary level and decommissioning of the secondary packaging barcode number is performed when the pharmacy receives the medicine.

EU FMD refers to the legal distribution chain in EU member states. In-hospital traceability is not a goal of the EU FMD. This implies that the FMD in itself does not support full traceability from the moment an individual unit of a medicine leaves the pharmacy to the point of administration to the individual patient. However, since the implementation of the FMD, experience has been gained on traceability and on the added value and some of the limitations of barcoding/barcode scanning, as will be explained in this document.

Developments and (national) guidelines supporting in-hospital medication safety, such as electronic prescribing, are a building block to achieving full traceability.

3. Scope of the document

a. Scope: in-hospital full traceability of medicines (individual units of a medicine) up to the point of administration to minimise the occurrence of medication administration errors and ensure patient safety (consisting of seven rights of medication administration: right patient, right medicinal product (right indication or approved indication), right dose, right time, and right administration route, right information and right documentation[1]).

b. Setting: Hospitals
The focus of this guidance document is on hospitals. However, traceability is valuable in all settings where medication is administered by care personnel in institutional care. In the not-too-distant future it is expected that traceability can be implemented in home care or in a 'virtual ward' (patients receiving hospital care in their home).

c. Disclaimer: most medication in a hospital will be prescribed by the physician (or other authorised prescriber) for a given time, dosage and route.
Some other medications, like ointments or drops (eye, ear, nose), may be given to the patient to self-administer. These types of medication administration may be excluded from the scope of this document.

d. Out of scope:
- Verification of authenticity of medicinal products entering the supply chain addressed by the FMD and Commission Delegated Regulation (EU) 2016/161.

[1] See for example Section 5.1 of EAHP's European Statements of Hospital Pharmacy - https://statements.eahp.eu/statements/final-statements

- Prevention of the entry into the legal supply chain of falsified medicinal products.
- Impact of repackaging/relabelling medicinal products at hospitals.
- Diagnosis and prescription of medicines.

4. Target audience

Policy-makers, national competent authorities, healthcare payment bodies (including insurance companies), hospital managers, healthcare professionals involved in the medication process (such as physicians, hospital pharmacists and nurses), IT staff (in-hospital and working in organisations supporting hospital IT) and patient associations.

5. In-hospital traceability system

This section focuses on track-and-trace in hospitals in terms of components/features of a complete track-and-trace system, development of such a system and systems that are already available. A medication cycle (prescribing, processing, dispensing and administering) that is electronic and automated as far as possible is also called a closed-loop medication process, a term commonly used in the UK.

Identification of (medicinal) products, for instance by labelling, increases their safe use. An identification label is designed to list several characteristics of the product, such as the name of the substance, strength, batch or lot number and expiry date. The overall purpose of labelling medication packages is to ensure their unambiguous identification and safe use, and to improve logistics and supply chain efficiency. The implementation of a system of harmonised standards supports efficiency and cost-effectiveness for manufacturers, suppliers and transporters. Traceability is improved through standardised procedures and standardised data. A national medicines data repository (such as the G-Standaard in the Netherlands)[2] makes it easier for all relevant healthcare stakeholders (including the prescriber and the hospital pharmacist) to access and use the same medication information.

From a clinical perspective, the aim of good medicine identification and labelling is to ensure that the appropriate medicine is selected for administration, leaving no room for doubt or error. At the point of administration, the identification (and recording) of the medication closes the loop to full traceability to the patient. In addition to the correct description of the medicinal product, this requires clear product identification and a robust recording system. This also supports the provision of information to ensure appropriate and safe storage, preparation, dispensing and administration. In the event of problems during the manufacturing, prescribing or dispensing process, the well-labelled and identified product can be tracked.

The importance of correctly recording both prescribed and administered medications is clear, and not just for patient safety. The registration of administered/used materials (used for a specific patient) can also be used for specific billing purposes. In addition, reimbursement policies may differ between public and private hospitals and are facilitated by correct recording.

Prescribing and administering are separate processes, each requiring its own registration process. At the level of the individual patient, the authorised prescriber prescribes the medication and registers this in the patient file and on an order form (or prescription). In a hospital, all prescriptions are checked by the pharmacist and then authorised (verification). Medication is stored in the pharmacy and, depending on the policy and organisation of the pharmacy, in decentralised medication storerooms in the hospital (under the responsibility of the pharmacist), where they are prepared for dispensing.

When the nurse prepares the medication for a specific patient, this will be registered in a specific system (such as a medication cardex). If procedures and systems are manual, full traceability cannot be achieved, as it would involve too many extra manual activities. For instance, individual patient records would need to be checked, the content of packages of medication in a ward or department would need to be counted and checked, etc. In addition, it is not technically feasible to record the specific identification details, such as lot number and expiry date for each individual medication administered. Digitised recording systems facilitate traceability and verification.

This guidance document recommends that full traceability can only be achieved in a digitised working environment and when each individual dose is correctly identified (barcoded), with all essential identification keys.

At present, only a small proportion of medicines entering a hospital are barcoded at the unit level. When a hospital implements point-of-care scanning, alternative procedures are required, such as relabelling at unit level in the pharmacy (e.g. through automated dose dispensing), a procedure that requires dedicated pharmacy personnel.

However, even in a fully digitalised hospital , traceability is not necessarily implemented for 100% of the medications. Based on risk and cost-benefit analyses, exemptions are defined, such as ointments (not barcoded at unit level and low risk) or inhalation medicines, drops (eye, ear and nose).

As relabelling requires extra personnel and can be seen as a risky procedure, some hospitals do not relabel, but the nurse (or pharmacy assistant) scans the barcode on the secondary packaging (in the ward's medication room) before dispensing, as this enables the lot and serial number to be traced to the

[2] https://www.z-index.nl/english

individual patient. This step is followed by scanning the patient's identification at the time of administration. However, this is an indirect process and requires regular reconciliation of the contents of the pack with the amount administered to patients, which can be time-consuming and burdensome.

Several systems have been developed to track medications:

- Türkiye has a well-developed system (the Pharmaceutical Track&Trace system ITS) that is well established for the purchase of medicines, their sale, for the consumption centres (such as warehouses, pharmacies, hospitals), their declaration of consumption and their verification. The focus of this system is a safe medication supply chain. However, the system was not originally developed to track medication in the clinical setting through to administration to individual patients.
- Multiple apps have been developed to support patients in managing medications, including remembering when and how to take them. These apps are consumer focused and have not been developed for use in a clinical setting.

- In Ireland, a system has been developed specifically for the management of haemophilia patients in their own home, including medication management control. The patient uses an app, and the national centre manages control-at-a-distance. This system is well developed, efficient, increases the safety of the individual patients, and is mainly used to support out-patient care of haemophilia patients.

A complete track-and-trace in-hospital system is not (yet) available on the market. Increasingly, electronic medical record (EMR) systems have built-in functionality to facilitate barcode scanning for verification, use a platform to store the barcoded data as master data, connect EMRs to other in-hospital IT systems, such as purchasing, pharmacy information or pharmaceutical warehouse management systems[3]. As the medicinal product and patient are reconciled with the prescription, this is also called a closed-loop system.

Scanning medicinal products as they enter the hospital and again as they are administered to the patient – without scanning the steps in between – is an example of an end-to-end tracing system[4]. This type of implementation ensures traceability to the patient and is less costly to implement but misses out on the direct advantages of full visibility and efficiency in the in-hospital supply chain (as mentioned above), which could lead to additional costs to expand the system in the future.

The implementation of the EU FMD is seen as supportive of in-hospital traceability, as the FMD results (for prescription medication) in package-level labelling with a scannable lot and expiry date. These are essential for traceability and patient safety.

Ideally, the standardised product information encoded in the barcode should be uploaded into the hospital's system by the hospital (or the hospital organisation). A standardised and harmonised system of barcoding and labelling that is applicable at all levels in a hospital is essential for traceability.

Such a system should be compatible with the requirements of the General Data Protection Regulation (GDPR). Data should only be used for traceability and not in any other way by stakeholders that are not directly involved in the process of dispensing/administering medicines.

6. Barcode Medication Administration (BCMA)

As explained in this guidance document, full traceability of medication in a hospital is best achieved through barcode scanning (at all levels of the medication process). The medication process is complex and can be designed in well-described steps with clear expectations of costs and benefits.
Barcode scanning of medication at the point of care can be achieved with BCMA. This section describes BCMA, including the specifics for success.

Originally developed for retail and supply chain purposes, barcode technologies are increasingly being used in other sectors, including healthcare. Barcodes are electronically readable identifiers that identify specifics of the product, such as the product itself, numbers (lot, batch and/or serial), date (expiry date). In Europe, regulation drives the identification of medicinal products with identifiers that are encoded in barcodes. For instance, from February 2019, as a result of the FMD, medicinal products entering a hospital will at minimum have an identifier on the secondary package consisting of at least a product code (allowing identification of at least the product name, the active substance, the pharmaceutical

[3] (translate into English): https://www.chipsoft.nl/oplossingen/139/HiX-voor-medicatie-en-apotheek
[4] (translate into English): https://www.uzleuven.be/nl/bedsidescanning

form, the strength, the pack size and the pack type of the medicinal product), the serial number, the batch number and the expiry date.

As well as supporting the medication supply chain, warehousing and stock-keeping, barcodes on medication can also be used effectively in direct patient care. When the nurse scans and thereby identifies the medication at the point of care (bedside), this process improves patient safety and reduces the risk of medication errors.

As the regulation requires identification with barcodes on the secondary packaging, this can be seen as a first step in improving patient safety. However, in a hospital setting, medications to be administered to an individual patient will not be taken from a secondary pack but will be administered in unit doses.

Therefore, full digitised hospital traceability requires additional barcoding and labelling operations at the primary packaging and/or single unit-dose level. The consistent availability of medication barcoded at the unit level reduces risky relabelling activities and would significantly increase (patient) safety.

Packaging/relabelling at hospital level requires much greater investment, as it must be done by every hospital and, because it involves considerable manual labour, has much higher running costs. At industry level it can be incorporated into the production process. Manufacturers will need to invest in their packaging and IT systems. It would be preferable for industry to adapt, acknowledging that patient safety is at the core of healthcare activities. Hospitals would also need to invest in hardware, software, training and infrastructure.

This context, and the absence of mandatory regulation of barcoding on the primary packaging of medicines, is the main reason for the lack of implementation of barcode scanning (and track & trace of medication) in hospitals. On this aspect, as only a limited number of hospitals had fully implemented bedside scanning during the administration of medicines, the Dutch Ministry of Health, Welfare and Sport commissioned Cap Gemini Consulting to conduct a cost-benefit analysison Barcoding on the primary packaging of medicines (Nov 2016: https://open.overheid.nl/documenten/ronl-archief-752101ad-99a9-444d-8d2c-af9e41491b9a/pdf).

Some large hospitals have voluntarily implemented a system of medication labelling down to the primary packaging unit level. This is an elaborate, rather high-risk process, requiring technology and dedicated personnel. The risks of relabelling should be weighed against the risk of medication errors. In fact, this consideration is patient versus process. Patient risks are significant but often are not noted or recognised. The process risk, such as relabelling, can be controlled more easily.

However, a barcode on the unit dose will allow the nurse to perform BCMA, confirming an appropriate check of identity, form of medication, dosage and time of administration. The technology should fit well with the work processes and be well implemented to support the safety of the medication administration processes. It is to be noted that BCMA cannot be implemented in a hospital that is still fully paper based.

A preliminary step for BCMA is identification of the medication unit dose. A linear barcode holds limited data/information; a barcode in Data Matrix format (2-dimensional) can hold more data, including lot and batch numbers and expiry date. In the EU, Data Matrix is currently the leading format for medicinal products.

BCMA requires the development of IT systems, such as the implementation of barcode scanning, barcode scanners that can process the identification data correctly, a portable or desktop computer with a wireless connection, a computer server, relevant software and interoperability of relevant IT systems, and a data warehouse.

When a nurse who is identified in the system administers medication to a patient in a healthcare setting, the nurse can scan the barcode on the patient's wristband to verify their identity. The nurse can then scan the barcode on the medication and use software to verify that he/she is administering the right medication to the right patient at the right dose, through the right route, and at the right time (the 'rights' of medication administration). BCMA was designed as an additional check to aid nurses in administering medication; however, it cannot replace the expertise and professional judgment of the nurse. The implementation of BCMA has been shown to significantly reduce medication administration errors in the healthcare setting[5].

[5] https://pure.rug.nl/ws/portalfiles/portal/3668356/Helmons_thesis.pdf

7. Processes

Medication safety is an important issue in hospitals, involving several stakeholders and multiple processes. A medication management process is actually a complex set of processes, and ideally consists of several steps, simplified as:

- defining the best treatment for the defined diagnosis and selecting the appropriate medication (physician);
- ordering/prescribing (prescribing or attending physician or authorised prescriber);
- verifying (pharmacist);
- dispensing (pharmacy personnel or nurse);
- distribution (pharmacy personnel or nurse);
- administration (nurse);
- monitoring of the individual patient (physician, clinical pharmacist, nurse, etc.), e.g. if the patient's condition deteriorates, it is possible to trace which medications were administered (or possibly forgotten);
- evaluating (pharmacist and physician).

The hospital formulary contains a selection of medications most commonly prescribed in the hospital and serves as a guidance document for prescribers. The hospital pharmacist is an important member of the hospital's Drugs and Therapeutics Committee (the name may vary), a multidisciplinary team in charge of selecting, discussing and deciding on the final hospital formulary. Important considerations include existing national formularies/lists of medicines, characteristics and needs of specific patient populations, state-of-the-art treatments, interactions, and a pharmaco-economic analysis.
This process requires a formulary management system with continuous updating and attention to formulary compliance (by both hospital pharmacists and prescribers).

Hospitals have a (central) main medication storage facility in the hospital pharmacy and smaller decentralised medication facilities near the point of care, such as departmental/ward medication rooms. The range of medications in decentralised locations is often 'general stock', not yet labelled for individual patients, and is limited to the specific medication for the type of patients expected in each particular department. For instance, a ward for neurological patients will have different medications in stock than a ward for surgical patients. In the event of an acute need for additional prescriptions (of medication not in stock on the particular ward), the medication could be ordered from the hospital pharmacy and delivered directly to the ward in the patient's name. Before administering medications, either a pharmacy technician or one of the nurses prepares the patient-specific medication according to the prescription (dispensing) in the medication room. In some countries, routine practice involves another nurse checking and then administering the medication to the patient. Any high-risk medication will officially require a double check and documenting of this double-check procedure. This is the case for oncolytic medication or opiates, for example.

Robots can be used in the in-hospital medication supply system, both in the pharmacy and in robotic dispensing cabinets on the wards. It is expected that more hospitals will use these robots in the future, as implementation is part of a positive business case, reducing pharmaceutical staff, reducing stock levels, reducing space requirements and reducing waste. Robots are not discussed further in this document.

Medication reconciliation is important when a patient is admitted to hospital. In many instances the processes of medication verification on admission, transfer and discharge are done by pharmacy staff, sometimes by nurses. The authorisation of these medications is regularly done by doctors. Eventually the doctor will write new medication orders (including continuation and, if needed, new prescriptions), starting the in-hospital medication process. As a rule, hospitalised patients are not responsible for storing/keeping their own medication supplies, nor are they responsible for the administration of medications.

Medications in a hospital setting are prescribed by the authorised prescriber, either in handwritten form or – preferably – as an electronic prescription. The hospital pharmacist checks all prescriptions in the pharmacy. Eventually, on the ward (or department) the nurse administers the medication according to the prescription, at the indicated time, in the correct dose, in the correct form and via the correct route to the correct patient. Administered medication is registered in the individual patient's record and in a specific medication system that can be reconciled to the required stock levels.

Hospitals that use paper files have manual procedures to register administration and for stock keeping. Hospitals using electronic files may have a completely electronic process, or mixed paper/electronic processes.

A digitised hospital will have interfaces between the different systems supporting the medication processes. Examples of such systems are:

- digital pharmacy systems (interfaced with lab systems, for verification purposes, for stock-keeping, etc);
- a digital formulary management system;
- a digital formulary that is connected to a clinical decision support system, connected to the computerised physician order entry (CPOE), connected or integrated in the EMR, connected to the Medication Administration System and to the BCMA;
- fully integrated systems covering all the above functions.

8. Phased implementation

In a voluntary implementation scenario, no hospital will be able to implement all the requirements of a medication traceability system immediately. Implementation cases show a mix of top-down and bottom-up approach.

Vision and strategy are as important as the commitment and understanding of medical professionals. In every hospital, the investment in an IT implementation must be balanced against other priorities.

Assuming the prerequisites are in place, such as a (to some extent) IT-developed hospital, the necessary hardware and software and trained staff, a well-defined phased approach will facilitate the implementation of a track-and-trace system and procedure. In practice, some patient care areas will benefit more from scanning barcodes than others. Several years ago, literature reviews already showed that BCMA results in a medication administration error reduction of 50%[6]. Sharing best practice information, including site visits to hospitals that have implemented BCMA, is a great way to learn and design the optimal implementation strategy for an individual hospital or even all national hospitals.

Priorities can be set using the cost-benefit ratio, with the benefit of implementing barcoding at unit-dose level exceeding the cost for expensive medications. Administration of oncolytic medication is an example of a process that is well controlled in hospitals (specific procedures in the pharmacy, guidelines to deal with waste, specific procedures for any related emergency, training of nurses) and is costly. The cost of oncolytic medication is high, the process is well controlled, and the pharmacy has a central role in almost the entire process. Spillage reduction and waste reduction will directly yield financial savings that can be better used to maintain and strengthen the quality of the healthcare services delivered by the hospital. For intravenous oncolytic medication, the final preparation is 'mixed' shortly before administration. Barcode scanning throughout the process from pharmacy through preparation and dispensing to administration at the point of care ultimately enables full traceability and increases patient safety. However, this describes a process that is already well controlled, and it entails only specific high-risk medication.

Priorities can also be set on a (known) risk ratio. Similar procedures can be designed for high-risk medication that is commonly used (and well known for patient safety incidents) like digoxin or methotrexate.

Another approach to consider is to select a specific ward as a pilot and design an implementation that will work for all medication that is used in this specific ward. If implemented well, this will greatly enhance safety for staff and patients and reduce the risk of workarounds. After evaluation, this implementation can be rolled out to other wards.

Preparation of medication and administration are steps that should be well distinguished. Both steps can benefit from identification and scanning.

Steps to be followed in a hospital to track-and-trace single unit doses until the point of administration include the following:

- business plan: make a plan to consider funding the implementation of hospital traceability;
- write a project plan for the specific implementation;
- important to note: not all hospitals or healthcare systems will be able to generate or allocate

[6] For instance: https://www.rug.nl/about-ug/latest-news/news/archief2014/promoties/promotie-p.j.-helmons_medication-safety-through-information-technology.-a-focus-on-medication-pr or https://research.rug.nl/files/3668356/Helmons_thesis.pdf

sufficient funds. Sometimes, there is a need for funding from sources other than hospital management, such as from national or EU funds;
- project ownership for implementation: hospital board in accordance with governing organisation;
- process ownership: the medication process involves practically all disciplines in the hospital.

Several actors can be identified for the overall processes and the separate steps. Defining clear responsibilities and addressing the correct actor is essential.

Action	Actor(s)
Being an ambassador of safe medication practices in the institution (including proactive pharmacovigilance)	Hospital pharmacists
Sharing the vision and benefits of safe medication practices Allocation of adequate budget. Actor: hospital board and finance department. Identify the 'early adopters' within the profession and within the hospital. Engaging and involving hospital management (at all levels).	Hospital board and higher management
Prioritising IT investments	Hospital board and IT department.
Involving IT department	Hospital board, head of IT, finance department. If present: CPIO
Define the required IT strategy, including selection of system(s), software and hardware	Head of IT department together with hospital pharmacist. Involve the procurement department.
Perform a gap-analysis to identify gaps and define scenarios to resolve gaps	Will depend on the local situation, in any case the IT department, the hospital pharmacist and the nurses
On arrival at the hospital pharmacy, only barcoded medication is received	Pharmaceutical manufacturer and supplier. In-hospital actor: hospital pharmacist (selection procurement and process design) and IT department (for hardware and software).
Engaging pharmaceutical staff	Hospital pharmacist.
Decision on level of identification and barcoding with relabelling to unit dose	Hospital pharmacist and hospital board
Engaging physicians	Hospital pharmacist and medical board
Engaging nurses	Hospital pharmacist, chief nursing officer, training department
Engaging other staff, such as logistics staff. Support the necessary change management	Human resources department and training department
Share the message and share the results to support commitment	Communication department

In addition to regular out-patient clinics and the treatment of these outpatients, in-patient stays are increasingly being shortened, while treatments are still ongoing. This leads to what are sometimes called 'virtual wards'. These offer future opportunities to extend point-of-care administration and full traceability of medicinal products to patients who are still under the full responsibility of the hospital, but are receiving their care at home or in another non-hospital setting.

9. Available systems

As in other sectors, in recent years digitalisation has progressed in healthcare, gradually replacing paper files and manual procedures. Any move forward in digitalisation involves risk assessment and change management. Hospitals are risk-prone environments; process changes need to be carefully designed to reduce risks. Resistance to change will have several causes: implementations that are perceived as beneficial for the nurse or the patient and do not add to the workload will be implemented more easily. In addition, technological implementations require safe and reliable technology and well-designed processes, or nurses (and physicians) will continue to use work-around processes, that have proven workable solutions in the past. A technological implementation, such as IT support,

implementing an EMR and barcode scanning require close observation of the original processes and supporting the advancement and improvement or redesign of these processes. It takes time to get medical personnel to understand the background and early stages of an implementation. However, changes and improvements that align well with the care processes will not only result in commitment, but also in safer processes and more time available for patient care[7].

As multiple entry points serve to facilitate and support digitalisation in a hospital, multiple systems are developed, each serving a specific need. Even within a hospital, multiple stakeholders may own a system such as 'the hospital, the pharmacy, or a specific department. As a result, IT in a hospital setting has evolved into a complex system of solutions, sometimes stand-alone, sometimes in a network (multiple systems from the same developer), and sometimes requiring interfaces for interoperability. This, of course, not only adds complexity, it also adds cost.

National guidance on the form of digitalisation varies between countries, adding to the diversity and overall complexity of achieving the goal of full in-hospital traceability. The aim of this European guidance document is to provide a summary of best practice and advice on how to implement it at operational, professional, standardisation and regulatory levels.

Concerning in-hospital medication, the hospital pharmacy is the starting point, as the central entry-point for medication. A pharmaceutical warehouse management system facilitates stock-keeping and procurement, for example. The barcode required by the EU FMD allows for better checking of the expiry date, contributing to patient safety.

Prescription orders should no longer be handwritten, but should preferably be issued electronically via the CPOE. A Clinical Decision Support System (CDSS) supports the physician in prescribing, via advice, alerts and reminders. Point-of-care reference information can be accessed via the internet, but ideally such a system is connected to or integrated with the hospital pharmacy system, enabling and facilitating the advisory role of the hospital pharmacist. The advisory role of the pharmacist can be enhanced by system links with direct patient-related parameters, such as laboratory results.

Any patient-related information (including prescription information) should be recorded manually in the patient file, or, in a digitised hospital, in the electronic medical record (EMR). Paper patient files often consist of multiple parts, a medical file for physicians' notes, a nursing file for nurses' notes and a medication card specifically to register administered medications. In a digitised hospital the medication card will be replaced by a medication administration system. The EMR should contain all of the information from these formerly paper files, facilitating multidisciplinary care and enhancing patient safety.

Interoperability is required with the CPOE, the medication administration system and with the pharmacy systems. The best option is to have CPOE, CDSS and pharmacy systems integrated with the EMR. Separate functions, but not separate systems. This hospital best practice requires some form of hospital-digitalisation.

10. Personnel and training

Digitalisation of a hospital requires a completely new section/department of IT professionals. If a hospital decides to have an in-house-developed EMR, the number of professionals will be large, including developers. If the hospital opts for an off-the-shelf EMR, fewer developers will be needed, but expertise to integrate the EMR with the in-hospital workflows will still be required. Next to technical IT expertise, support expertise is needed and experts such as data-analysts.

Practice shows that to achieve full traceability of medications up to final administration to patients requires changes to systems and workflows, and involves several types of healthcare professionals. This requires an understanding of responsibilities, workflows, risk analysis – including connecting (exchange) moments – and ultimately full alignment. In effect, this is major change management. Any implementation will therefore benefit from the (orderly) involvement and commitment of representatives of all affected staff, both in the design phase and in the implementation.

The expertise of healthcare professionals is primarily in 'caring and curing', and their focus is not necessarily on processes or interactions. The working conditions for medical professionals, and thereby the basic conditions for a patient-centred environment, should be ensured by appropriate IT and technical as well as construction/building capacity infrastructure.

[7] https://pure.rug.nl/ws/portalfiles/portal/3668356/Helmons_thesis.pdf

Moving to a more digitised working environment requires not only adapted procedures, but also a cultural change. A “scanning culture” should be developed, to discourage workarounds as much as possible, since workarounds add risk to the processes and potentially to the patients. Redesign of processes and design of the system should lead to scanning as the easiest pathway. In a scanning culture the goals of traceability and scanning should be clearly communicated, and scanning compliance should be monitored on a regular basis. Analysis of warning overrides should be performed on, e.g. a weekly basis, systems/processes should be evaluated, fine-tuned and, where necessary, feedback provided to staff involved in the process. Since processes interact constantly with each other, monitoring and fine-tuning is a continuous effort to establish a safe and workable situation.

In a hospital, medication safety is the responsibility of several stakeholders and professionals, so the sequential flow of medication through the hospital needs to be central to the decision process, and the training process. Each stakeholder needs to be fully confident that all responsibilities are performed correctly through a chain of trust, so that they can rely on safe systems and on the previous professional in line, and feel trusted by the next professional in line.

Whether a hospital is a ‘paper world’ or fully digitised (and all possible variations in between) a good overview of the workflow processes and the stakeholders is paramount. In practice, even if the high-level processes are similar, each hospital will have its own workflows and processes. Understanding these is essential for successful change management processes.

Implementing traceability requires change management and understanding the effect of changes on the medical professionals and other hospital staff. This can be addressed in training, which (in part) needs to be tailor-made for the specific target groups. To achieve the necessary change management in a hospital, this type of training should not be voluntary, but compulsory.

Training is not just required for prescribers and nurses, but also for pharmaceutical staff, as they have an essential role in ensuring the correct medication is available, checking prescriptions and uploading safety warnings into the system. Training should also include staff in logistics, in IT, physicians and staff in administration and management. Training should preferably also include purchasing staff, warehouse staff and logistics management.

In order to ensure the long-term implementation of full hospital traceability, training must be extended to educational organisations and universities. Future generations of healthcare professionals (such as clinical support staff, hospital pharmacists, quality assurance professionals, nurses and physicians) should be suitably trained in the understanding and use of IT tools and on traceability in order to ensure successful implementations and to lay a foundation for continuous innovation.

Training in a healthcare environment will always require continuous attention and is an ongoing process.

11. Premises and equipment

Equipment needed for the implementation of full hospital traceability includes barcode readers and interoperable IT systems that can process the scanned data. Their efficient use requires the use of ubiquitous standards, e.g. for the generation of identifiers and barcodes. The advantage of a global system of standards (such as GS1) is the applicability throughout the hospital and the healthcare supply chain.

With the GS1 standards, identification keys are converted to machine-readable data carriers (barcodes) so the encrypted information can be read automatically. These standards are system agnostic and can be built into IT systems. This system has developed (global) standards for, among others, product identification, asset identification, locations, transactions, processes, relations and all required identification keys (such as expiry date, lot and batch numbers). A linear barcode has limited data capacity; increasing demands for data capacity may result in multiple linear barcodes on a pack, which can be confusing as to which should be scanned for what purpose. Innovations of the original linear barcode as a data carrier and adjustments to match the (increasing) data requirements of a specific sector have led to the development and implementation of 2D data carriers (such as DataMatrix). The DataMatrix contains much more information in one scannable symbol, making it easier to capture information and simplify the scanning process.

Throughout this guidance document, reference is made to necessary steps, equipment, etc. This section summarises the essentials. No further details are added, as the details depend on the specific

conditions and situation in a given country and/or hospital.

To achieve traceability of medicinal products in a hospital, at least the following are required:

- Understanding the need to standardise and that standardisation facilitates IT implementation in hospitals.
- Barcoded medications (from the manufacturer) with harmonised details included in the barcode at unit-dose level (product details, lot or batch number, expiry date).
- Identification at correct product/package level (to prevent relabelling).
- Development of IT, including necessary interfaces.
- Implementation of a patient identifier (and preferably a staff identifier).
- Desktop computers and mobile devices (laptops, tablets and mobile phones) in sufficient numbers.
- Including medication trolleys for the nurse to use during the medication round.
- In-hospital computerised systems, that have interfaces and are interoperable.
- Data warehouse for storing data.
- Allowing/building IT interfaces and exchange of data and translating data into information.
- Secure Wi-Fi environment.
- Barcode scanners with the correct capabilities and configuration.
- Printers (document printers as well as label printers).
- For any IT-related system, redundancy/back-up is an important necessary aspect.

12. Potential obstacles to development/implementation of full traceability

As described in the previous sections, digitalisation and barcode scanning can be considered important innovations in hospitals and are also needed for the purpose of medication traceability. Processes are similar in all hospitals. However, as circumstances vary from country to country and hospital to hospital, the perceived challenges and barriers may vary. This section gives an overview of potential obstacles.

A lack of regulation on barcoding at the primary packaging level poses an important threat to the goal of full in-hospital traceability. Stakeholders, such as manufacturers, can decide to simply comply with barcoding/identification at the secondary level (as regulated by the FMD) or go beyond to barcode the medications at the primary packaging level. Hospitals can opt to scan at the bedside only those medications that are barcoded at the correct level and register the rest manually or invest in the relabelling of all medications. Obviously, in practice, either of these situations allows for permanent gaps, implying incomplete traceability.

The availability of the correct IT infrastructure and the necessary peripheral equipment is an important precondition for any traceability programme. Experience shows that before starting a traceability programme in a hospital, some practical issues need to be addressed. This guidance document addresses some of these. This section lists some of the practical issues collected by the drafting group that are identified as weaknesses:

- Identification/barcoding at the pack level, requiring alternative ways to scan the correct barcode at the point of care, such as relabelling, scanning packages from which a single unit is taken ('indirect scanning') to be administered to the patient, or entering the administered dose manually.
- Unscannable barcodes (damaged or misplaced).
- Hybrid situations in hospitals, partly handwritten records and partly digitised procedures.
- Lack of knowledge among the medical and nursing staff of 'practical automation', such as the use of electronic records.
- The assumption that medical personnel can automatically change their way of working without proper training.
- The assumption that medical staff automatically understand which barcode on a pack should to be scanned and why.
- Pharmaceutical products with incomplete barcodes: identifiers that lack a lot/batch number and/or lack the expiry date.
- Processes that allow workarounds, resulting in incomplete registration, an increase in patient safety risks and the prevention of full registration, which hinders traceability. This can happen in acute care situations, for example.
- Mixed processes, more specific procedures that are partly manual and partly use scanning. This is especially risky if these processes also allow workarounds.
- Mistakes in the process redesign leading to workflows disrupting processes.
- In some hospitals "over-alerting" (interactions/dose checker/contraindications) is an issue. This can cause additional 'digitalisation fatigue' among healthcare personnel and should be addressed and avoided throughout the process of using decision support systems and EMRs.

Costs (high-level considerations):

Digitalisation has benefits and costs. Time is needed to transform all aspects of healthcare from a paper reality to a fully automated digital reality. This involves changes for each stakeholder. As healthcare is a 'chain', ideally each stakeholder understands the effect the changes will have on the processes of the next stakeholder in the chain. For instance, a barcode on a product should be labelled in such a manner that barcode scanning can be done easily, and the barcode should hold all necessary identification keys. An EMR in itself is not enough to allow for barcode scanning at the bedside, barcode scanners that can process the data are needed as well as the previously mentioned IT systems.

Given the variety of hospital systems, the variety of digitalisation and the complex IT market, it is difficult, if not impossible, to estimate the investment required to reach the goal of full medication traceability in hospitals. In some countries, software providers are increasingly offering scan capability embedded in their software. This is an important development that will help to ensure that only hospital IT systems that support barcode scanning and traceability will be used in the future.

EMR systems that are available on the market are costly (millions of euros for purchase and implementation), excluding the training of staff and other internal costs. Interfaces with other IT systems are essential and, depending on the solution provider, these are sometimes costly. In addition, all systems require an adequate budget for maintenance and updates.
An in-house built EMR system might seem less expensive, but requires a great number of dedicated in-house IT staff, and also requires maintenance, updating and interfaces. For hospitals already equipped with an EMR, the additional costs (scanners, training, etc.) to achieve full traceability are much more limited.

Any cost-benefit analysis must include direct costs (such as hardware, software and data storage) and indirect costs (including manpower, training and maintenance). The same is true for benefits, such as the potential gain in staff time by reducing manual procedures, and capitalising on improved patient safety (e.g. reduction in hospital in-patient days, reduction in medication errors). Any cost-benefit ratio will depend on the (quality of) care issues that are to be improved.

A developed business case per country could provide a rough overview of the costs and benefits involved, given the specific IT context of the country. Some countries have already outlined a policy on digitalisation in healthcare, such as the UK's National Health Service (NHS) digital[8].
Some benefits are:

- improved patient safety, including reduction of medication errors,
- increased efficiency in several processes,
- efficiency in pharmaceutical supply chain management, including reduction of medication stock,
- better and real time information for national medicines monitoring systems, supporting rationalising procurement,
- reduction of waste due to better stock management , e.g. for a better monitoring of expiry dates,
- nurses' time given back to care,
- time given back to hospital pharmacists and their staff,
- better monitoring and evaluation of medical processes,
- possible increase in medical productivity.

In addition to the above-mentioned benefits, reductions in paper use, printer facilities and other long-term benefits contribute to sustainability goals.

No hospital will be capable of immediately implementing everything required for a medication traceability system. In part, the investments can be recouped through waste reduction and hours given back to care. If each step in a designed process is well described, costs and benefits can be compared/balanced per step.

Guidance, including sharing of good examples, is needed to understand both costs and benefits.

13. Quality assurance

For all stakeholders, an important aspect of healthcare is quality. Quality can also be considered an important aspect of patient safety, or patient safety can be considered an aspect of quality. Healthcare professionals work with professional guidelines in which quality is embedded. Hospitals will have a quality department and dedicated quality staff in specific departments, such as the laboratory, the

[8] https://digital.nhs.uk
https://digital.nhs.uk/services/digital-and-interoperable-medicines/resources-for-health-and-care-services/other-resources/strategic-drivers

pharmacy and wards.

Quality assurance and quality monitoring are two sides of the same coin. Quality assurance originates from the manufacturing industry, establishing and maintaining set requirements for developing or manufacturing reliable products. Quality monitoring supports the evaluation of processes, and checks the desired outcome against the actual outcome, supporting continuous improvement. Quality assurance and quality monitoring are widely used in healthcare and hospitals to improve work processes and efficiency and to meet the needs, expectations and requirements of both clinicians and patients.

The implementation of well-tested procedures, protocols and standards is part of continuous quality improvement. In the field of medical work, implementing and maintaining a quality assurance programme helps prevent errors before they happen.

In order to meet the requirements for a well-functioning implementation of bedside scanning, there are some important conditions that are not only specific to bedside scanning, but to the proper functioning of the hospital, e.g.:

- A good quality system needs to be implemented.
- Personnel must have an appropriate level of training and can only perform tasks for which they are authorised.
- Automated systems must be secured with adequately functioning back-up systems.
- All areas where medicinal products are stored must be controlled and monitored for appropriate climatic conditions and authorised access.

As hospitals move from manual processes to IT-supported processes and IT-supported administration and registration, more and more data become available. Data are less meaningful if they cannot be interpreted or shared (requiring interoperability of systems and a well-functioning data warehouse). Standardisation of what is incorporated in data, and how data are obtained and shared/exchanged are examples of quality assurance of IT systems.

The implementation of global standards facilitates the exchange of unique data in a uniform way, using the same definitions and descriptions.

Although each patient's situation is unique,, healthcare delivery benefits from standardisation, as this increases the reliability of processes and procedures and supports state-of-the art clinical pathways. Bedside scanning requires standardisation and is IT-supported. For the success of digitalisation and IT, standardisation of procedures and processes is essential. Digitalisation facilitates the transformation of data into useful information, supporting several processes, logistic, administrative as well as clinical. Data use and transformation also requires standardisation of definitions, reduction of 'free text' in patient records, and good data processing. Good implementation of standards is essential to enable data processing and, for example, interoperability of systems and data exchange. Hospitals benefit from the digital exchange of product data with the manufacturers and suppliers for purchasing purposes. For drug information, national and international databases form an indispensable source. However, patient-related data (traceable to the individual patient) must be protected in the hospital environment and safeguarded from unauthorised access by external stakeholders.

The hospital must add/embed the above-mentioned processes and procedures in their quality system. Hospitals are responsible for creating a "scanning culture" in which workarounds should be discouraged as much as possible. Some components of a scanning culture include:
- processes are designed so that they encourage scanning;
- the goals of traceability and scanning are clearly communicated;
- scanning compliance is checked on a regular basis;
- analysis of 'warning overrides' is performed on, e.g. a weekly basis;
- records and Analysis of non-compliance;
- system/process is evaluated, fine-tuned and developed;
- when needed, feedback is provided to staff involved in the process.

Regular reports to management and the board ensure that quality and safety receive the required attention at all levels. Internal audit systems add to quality assurance. These audits can be administrative (or on separate parts of the administrative processes), on logistics (including the mandatory control at reception and the labelling control after unpacking), and on patient pathways or even on patient-related outcomes.

External accreditation or certification of a hospital is increasingly seen as a guarantee of public quality

assurance. Accreditation organisations are active in several countries. In recent years, some global accreditation organisations (such as Joint Commission International (JCI), Accreditation Canada) have taken a large share of the market. In some countries a successful accreditation procedure has been made mandatory by regulation for hospitals. A positive accreditation result is usually valid for several years. These procedures involve costs for the accreditation process itself and internal costs, e.g. for staff.

One such accreditation organisation is the Healthcare Information and Management Systems Society (HIMSS). HIMSS has developed several maturity models, one of which, the Electronic Medical Record Adoption Model (EMRAM) specifically focuses on electronic medical records. EMRAM is designed to measure clinical outcomes, patient engagement and clinician use. Stage 7 is the top level of this maturity model. The audit procedure for stage 7 checks whether the hospital has implemented barcode scanning in their procedures. As described, 'EMRAM ensures the workflow and content in the digital tool meets the needs of the clinical teams while monitoring compliance with approved standards.'

To become a 'stage 7 HIMSS hospital' electronic traceability of medications is a requirement, illustrating that institution-wide traceability is very much possible. In 2022, several European hospitals reached this level of validation/accreditation[9].

14. Regulation

The safety of patients, healthcare professionals and products used in healthcare (such as medicinal products, medical devices and health IT) is subject to regulation. In principle this governs actions or procedures and requires an authority to oversee the organisation or system. Healthcare, of which hospital care is a specific part, is subject to several levels of regulation.

In the absence of regulation, professional standards are set by scientific associations of medical professionals (increasingly aligned internationally), which promotes equal quality of care for all patients.

National governments establish and enforce national regulations and legislation, for example, requirements for the recognition of professional qualifications in their healthcare system.

International and national healthcare regulations are important drivers to ensure adequate qualification and training of healthcare professionals and quality of care, healthcare products and healthcare IT systems.

Through their governmental enforcement role, healthcare inspectorates support public health by ensuring a high level of quality assurance in healthcare establishments. This also gives governments access to data useful for establishing and maintaining healthcare policies and, to some extent, cost control.

For EU member states, national legislation is supplemented by EU directives, which must be transposed into national law, and EU regulations, which are directly applicable in all member states. There is currently no requirement covering full traceability of medicinal products in EU directives or regulations.

The implementation of the EU FMD has created a focus on the logistics chain. Although the purpose of the FMD is to prevent falsified medicinal products from entering the supply chain, the FMD has in fact raised awareness of the issue of traceability of medicinal products and the possibility of achieving traceability to the patient. All stakeholders – including manufacturers – are faced with the costs of implementing barcoding and adapting procedures. The benefits lie in patient safety, but also in efficiency.

However, the FMD has mandated coding of medicinal products at the secondary packaging level and will not mandate coding at the primary packaging level. It is important for all stakeholders to understand this 'missing link' to reaching full traceability and to work together towards a harmonised solution.

A national example of a next step can be seen in the UK. A recent consultation on 'point-of-care manufacturing'[10] is a preparatory step towards new legislation that is aimed at supporting increased manufacture of point-of-care products while ensuring that these products achieve the same assurance of safety, quality and efficacy that currently exists for more conventional medicinal products. A new

[9] https://www.himss.org/news/himss22-europe-celebrates-healthcare-systems-validated-emram-stages-6-and-7

[10] https://www.gov.uk/government/consultations/point-of-care-consultation/consultation-on-point-of-care-manufacturing

regulatory framework has been proposed, based on and linking with current regulatory systems for medicines approvals, clinical trials, evaluation of regulatory compliance at manufacturing sites and safety monitoring[11].

This can be seen as the first framework of its kind to facilitate the manufacture of innovative medicines at the point of care, which will facilitate point-of-care (bedside) scanning.

15. Data protection and data sharing

The EU GDPR has been in force since May 2018. For national authorities, the GDPR is fundamental to the development and implementation of national privacy regulation. Protection of data is an important focus of the GDPR. This regulation applies to a 'paper world' as well as to the 'digital world'. Principles that were already part of good practice are now regulated in the GDPR.

Some of these principles align well with the requirements for a full medication traceability system. Some require extra attention. For example, when processing personal data, one of the principles is data minimisation, in other words, the processing of data must be 'adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed'.

Any healthcare-related system that uses data, generates data or holds data must be compatible with the requirements of the GDPR. Personal patient-related data must always be protected, so that it is only accessible to the treating healthcare professionals. In terms of traceability, healthcare-related data should only be used for (product) traceability purposes (such as in-hospital reconciliation of the prescribed drug versus the administered drug) and not in any other way by stakeholders that are not directly involved in the process of dispensing/administering medicines or treating the specific patient.

If this is transposed to a hospital setting, personal patient data must be accessible to the relevant (and authorised) caregivers. The hospital is obliged to construct safe systems of access to patient data, and audit and monitor these. This requires both paper and digital systems. Consent of patients is needed for any exchange of personal data with third parties. In line with this principle, medical professionals who are not involved in care processes for any given patient are considered as third parties, and therefore have no right to access and process data from this patient.

Another important principle is integrity and confidentiality: data must be 'processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.' Hospitals must comply with this principle.

Aggregated healthcare data can be used and shared, for example, for research, treatment evaluation, national or international medical related registries and healthcare policies. These opportunities leverage great benefits. However, these aggregated data must be anonymised in a format that cannot be traced back to individual patients.

In cases where traceability to specific patients would be necessary (e.g. in the case of serious and harmful side-effects of a treatment), the hospital must trace the individual patients without disclosing their personal data elsewhere.

When designing and implementing barcode scanning and bedside scanning, the GDPR guidance must be respected by all stakeholders.

[11] https://www.gov.uk/government/news/uk-to-introduce-first-of-its-kind-framework-to-make-it-easier-to-manufacture-innovative-medicines-at-the-point-of-care

16. Recommendations

Background to the recommendations

- Developments and (national) guidelines supporting in-hospital medication safety, such as electronic prescribing, are building blocks for achieving full traceability.
- Ensuring full in-hospital traceability raises concerns about the demands on the hospital's infrastructure. Elements such as scanning points, medication trolleys, barcoded products, patient identifiers and on-screen alerts are not always in place, depending on the hospital. Introducing and implementing traceability of medicinal products in a hospital is a complex and costly process. Overall, the costs of this process are expected to initially outweigh the immediate benefits. Capitalising on the expected medium- and long-term benefits will help to build a strong business case. For the healthcare supply chain, the benefits are quite well documented. More research and publications on this topic in the hospital environment will be helpful[12].
- All stakeholders should be aware of the investment cost for the implementation of full in-hospital traceability with barcoding of medicinal products at the primary level, to be balanced by benefits at other levels of the healthcare systems. This will be made possible through co-operation on harmonised solutions, such as agreeing upon a universal standard.
- Hospital processes tend to have risky moments and gain quality through routine and standardisation. Any process change needs to be 'thought through', and designed to be as non-disruptive as possible. To introduce traceability in the medication process from pharmacy to administration to the patient requires process redesign. Describing the various steps in the medication processes, and deciding on which IT support/system is needed for which step, requires both IT expertise and insight/expertise in the actual work processes. Depending on previous related IT decisions (such as which EMR is selected) each step requires a decision about interoperability, immediate benefits and expected future benefits. If the medication processes are well designed with IT support, the actual bedside scanning is the final step and probably the least costly. In a business case, the direct and indirect financial implications must be capitalised.

<u>Recommendations for specific stakeholders:</u>

Policy-makers and regulators (medicines and hospitals), at EU and national levels

- Being aware that digitalisation in healthcare is greatly enforced by regulation,
- Being aware that the financial margins of healthcare providers (especially the public ones) are small and implementation may need to be facilitated or supported,

it is recommended that policy-makers

- establish a regulatory framework for digitalisation, including interoperability of systems and safe back-up systems,
- take harmonised measures across Europe to avoid multiple systems with issues of interoperability,
- based on the evidence of the impact of regulations on in-hospital traceability on patient safety and of the accompanying cost-benefit, establish regulation for unit-dose barcoding of all authorised medicinal products. It is acknowledged that in the absence of regulation, only equipped and resourced hospitals would be able perform unit-dose relabelling with barcoding allowing in-hospital traceability.

Industry (pharmaceutical manufacturers, solution providers, industrial third parties)

- Recognising the efforts made by stakeholders from industry to support patient safety and the need for these efforts to be continued,

it is recommended that pharmaceutical manufacturers, with the support of their solution providers and other industry third parties:

- implement the regulatory requirements for barcoding unit doses, facilitating full in-hospital traceability,
- ensure that their monitoring systems in packaging lines and in quality control guarantee that barcodes are scannable at the next level (hospital) and placed at the correct scannable location,
- ensure that the barcodes include all relevant data, such as product code, batch number and expiry date, as these need to be included in the in-hospital traceability systems.

Hospital boards

- Considering the awareness of hospital boards of the topic of full in-hospital traceability, specifically

[12] Implementation of barcode medication administration. (BMCA) technology on infusion pumps in the operating rooms. BMJ Open Quality 2023;12:e002023. doi:10.1136/bmjoq-2022-002023.

IJQHC Communications, 2021, 1(1), 1–3; DOI: https://doi.org/10.1093/ijcoms/lyab014. Use of barcode technology can make a difference to patient safety in the post-COVID era

of its benefits (on top of efficiency) for patient safety,

it is recommended that hospital boards:

- share (and facilitate the sharing of) best practices and use cases,
- define their needs with policy-makers and payment bodies in order to generate funding for the investments to be made (infrastructure, human resources, training, etc.),
- ensure a quality culture is in place (including quality departments and quality systems) to support the implementation of in-hospital traceability,
- consider the training required to design and implement a secure system of full traceability.
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IT managers/IT service providers

- Acknowledging the responsibility of IT managers for the redesign of the IT system supporting the implementation of in-hospital traceability and involve healthcare professionals to establish safe and lean workflow processes,

it is recommended that IT managers:

- facilitate and create interoperability between the various IT systems (current and future),
- ensure proper data management with respect to GDPR.

It is recommended that IT service providers:

- ensure that each IT system developed supports both barcode scanning and the processing of scanned data such as product code, batch number and expiry date, as these are required for inclusion in the in-hospital traceability systems,
- ensure interoperability of systems and data warehouses and prevent (or at a minimum reduce) vendor lock-in.

Hospital quality management departments

It is recommended that quality management departments:

- support the hospital board in understanding the need for the capability and capacity of the development of the traceability function,
- support hospital management and departments through the development of quality procedures for the implementation of in-hospital traceability,
- inform and train hospital staff on developments to implement identification of medicines in these IT systems and on the alignment with national and international accreditation systems and with hospital and pharmaceutical regulations,
- ensure the quality of the traceability function/system through auditing, failure analysis, evaluation and support for accreditation.

Hospital pharmacists

- Recognising the important role played by hospital pharmacists and their professional associations, both nationally and internationally, in raising awareness and sharing good practices for the business case for implementation of full in-hospital traceability,

it is recommended that hospital pharmacists:

- take an active part along with other healthcare professionals in providing hospital boards with evidence about the benefit of in-hospital traceability for patient safety,
- are involved and combine efforts with other healthcare professionals in the redesign of the processes ensuring implementation of full in-hospital traceability, including for the reception of medicines,
- ensure in their hospitals that conditions are met to allow bedside scanning.

Other healthcare professionals in the hospital (such as physicians, nurses)

- Recognising the role played by all healthcare professionals in raising awareness of the importance of full medication traceability,

it is recommended that other healthcare professionals:

- take an active part in providing hospital boards with evidence of the benefit of in-hospital traceability for patient safety,
- combine efforts to develop and implement process redesign to ensure the implementation of in-hospital traceability, e.g. for the roll-out of a pilot in their own hospital.

Healthcare payment bodies (NHS, insurance companies, etc.)

- Considering the awareness of healthcare payers that achieving benefits from any change requires investment, for which not all healthcare providers and hospitals will have financial resources,
- Recognising that healthcare payers have to inform themselves about the benefits of full in-hospital traceability and must be involved in its establishment by providing them with examples and business cases,

it is recommended that healthcare payment bodies:

- ensure the investments necessary are made in piloting, developing and rolling out full in-hospital

traceability,
- take up a leading role in facilitating the sharing of good practice cases, knowledge and expertise,
- encourage hospitals to implement full in-hospital traceability.

Patients
- Considering that patient organisations, both nationally and internationally, need to be aware of the benefits of barcode scanning for patient safety,

it is recommended that patient organisations:
- strongly advocate for in-hospital traceability by stressing the importance of the topic at all levels in which they are involved.

Note for Committees' review: standardisation bodies (e.g. HIMSS, JCI) have not been considered as suitable targets for recommendations in this guideline document, at least at this stage, as accreditation of in-hospital traceability could significantly add to investment costs. However, they could be involved in the public consultation.

17. Definitions

This section provides definitions specifically for the purpose of this guidance document.

Adverse drug event (ADE): any injury secondary to medication use.

Administering medication: point-of-care process involving the direct application of a prescribed medication – whether by injection, inhalation, ingestion or other means – to an individual patient by an individual person legally authorised to do so.

Barcode: a symbol that can be scanned electronically using laser or image-based technology. Barcodes are used to encode information such as key identifiers (product, shipment, location, etc.) and key attributes (serial numbers, batch/lot numbers, dates, etc.). The most commonly used standard for barcoding identification in Europe is GS1, using GS1 syntaxes (plain, GS1 element string and GS1 Digital Link URI)[13]. Linear barcodes (one-dimensional) and increasingly two-dimensional (2D) barcodes (such as the Data Matrix) are used in healthcare.

Referring to medicines entering the hospital in accordance with the FMD: "The barcode shall be a machine-readable Data Matrix and have error detection and correction equivalent to or higher than those of the Data Matrix ECC200. Barcodes conforming to the International Organization for Standardisation/International Electrotechnical Commission standard ('ISO/IEC') 16022:2006 shall be presumed to fulfil the requirements".

Barcode Medication Administration (BCMA): identification of medication at the bedside/point of care using barcode scanning.

Cardex: originally the proprietary name for a filing system for nursing records and orders that was held centrally on the ward and contained all the nursing details and observations on patients that had been acquired during their stay in hospital.

Clinical Decision Support System (CDSS): health IT, primarily used at the point of care, intended to improve healthcare delivery by enhancing medical decisions with targeted clinical knowledge, patient information and other health information. CDSS encompasses a variety of tools to enhance decision-making in the clinical workflow.

Computerised Physician Order Entry (CPOE): the process of a medical professional entering and sending medication orders and treatment instructions electronically via a computer application instead of on paper charts. This advantageous format reduces errors related to the ambiguity of handwriting or transcription of medication orders.

Dispensing medication: preparing medication for administration to the patient according to the prescription.

Double check (verification in a double procedure): making certain that an item or a process is correct or safe, usually by examining it again (four eyes principle). In the specific case of medication, checking if the prepared medication is correct according to the prescription before administering to the patient. Double check can be performed by another healthcare professional or by a safe system-check, such as an IT solution to support verification, like barcode scanning.

Electronic Medical Record (EMR): technology that enables the storage, retrieval and modification of health data using digital means instead of paper-based recording systems within one healthcare organisation or hospital. An EMR is a software application/system that replaces paper patient records, stores patient information digitally and makes this information available to authorised users in real time. Its purpose is to securely support care processes.

The EMR should interface with other IT systems, such as the laboratory information system, the hospital pharmacy information system, the electronic prescription system, the CPOE, with data back-up provided, etc.

EMRs can be either in-house developed or purchased from specialised EMR developers (who provide maintenance). Since clinical workflows and working habits vary from hospital to hospital, EMRs need to be customised to reduce the risks to patients from the handling of records by healthcare professionals (physicians, hospital pharmacists and nurses).

[13] https://www.gs1.org/standards/barcodes

Electronic Prescription System: computer-based electronic generation, transmission and filling of a medical prescription (including authorised access), replacing paper and faxed prescriptions.

Electronic Medical Record Adoption Model (EMRAM): the HIMSS EMRAM measures clinical outcomes, patient engagement and clinician use of EMR technology to strengthen organisational performance and health outcomes across patient populations. The internationally applicable EMRAM incorporates methodology and algorithms to score a whole hospital, including in-patient, out-patient and day care services provided on the hospital campus. EMRAM scores hospitals around the world relative to their digital maturity, providing a detailed road map to ease adoption and begin a digital transformation journey towards aspirational outcomes. Measuring evidence-based data at each stage, organisations use EMRAM to optimise digital work environments, improve performance and financial sustainability, build a sustainable workforce, and support an exceptional patient experience. Leveraging information digitally improves patient safety and clinician satisfaction by reducing errors in care, length of stay for patients and duplicated care orders, and streamlining the access and use of data to inform care delivery.

Falsified Medicines Directive (Directive 2011/62/EU, FMD) and Commission Delegated Regulation (EU) 2016/161: EU rules for the prevention of the entry into the legal supply chain of falsified medicinal products. The FMD is implemented in EU member states.

Formulary: a hospital-specific selection of drugs/medications (covering all required therapeutic areas) that can be used in the hospital to assist in the selection of the correct medication. A formulary may be in printed or digital form.
In a hospital, the selection of pharmaceutical products, among which medications, is the responsibility of Drugs and Therapeutics Committees, that are multidisciplinary teams in charge of selection and of which the hospital pharmacist is an important member. Physicians take part in these committees to discuss and decide on the final hospital formulary. Important considerations include existing national formularies/list of medicines, characteristics and needs of specific patient populations, state-of-the-art treatment, interactions, and the pharmaco-economic analysis. The in-hospital selected pharmaceuticals are basis of the hospital formulary, that contains a list of medications most prescribed in the hospital and serves as a guidance document for the prescribers.

This requires a formulary management system, continuous updating and attention to formulary compliance (by the prescribers and the hospital pharmacists).

General Data Protection Regulation (GDPR): regulation in force from 25 May 2018 in all member states to harmonise data privacy laws across Europe[14].

Hospital Information Management System (HIMS): a unique system that tracks all operations in a hospital and often comprises a combination of software used for administrative purposes and software used for clinical purposes by different professionals. Patient-related identification details, investigations, laboratory and pathology results, operating room processes, hospital pharmacy operations and human resources processes are included. Electronic medical records (EMRs) containing the medical and nursing history of individual patients, can be part of the HIMS or can be connected via interfaces.

Healthcare professional: a trained and licensed professional, such as a Doctor of Medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist, or another professional exercising activities in the healthcare sector.

Healthcare provider: often used interchangeably to refer to either an individual healthcare professional or an organisation that offers healthcare services.

Healthcare Information and Management Systems Society (HIMSS)[15]: not-for-profit organisation that develops IT standards[16] to help reform the global health ecosystem. Among others, HIMSS drives the adoption of standard-based interoperability to improve the way healthcare systems share information for optimal care; and provides educational and professional opportunities to prepare the next generation of

[14] https://gdpr-info.eu
[15] (www.himss.org/who-we-are
[16] Clinical Supply Chain Outcome Model (CISOM): https://www.himss.org/what-we-do-solutions/digital-health-transformation/maturity-models/clinically-integrated-supply-outcomes-model-cisom
Electronic Medical Record Adoption Model (EMRAM): https://www.himss.org/what-we-do-solutions/digital-health-transformation/maturity-models/electronic-medical-record-adoption-model-emram

health information and technology leaders for the digital health workforce.

Identifier: a character or group of characters used to identify or name a series of associated data. Digitalisation facilitates the readability, storage and exchange of the data in an identifier. A barcode is a data carrier for identifiers.

Information technology (IT): a broad (still evolving) concept that covers any product that will store, retrieve, manipulate, transmit or receive information electronically in a digital form (e.g. personal computers, including smartphones, digital television, email and robots).

Integrating the Healthcare Enterprise (IHE): international not-for-profit organisation that has published several documents on traceability of medicines in hospitals[17].

Joint Commission International (JCI): US-based international organisation in healthcare/hospital accreditation[18] .

Labelling: information on the immediate or outer packaging.

Medication error: any mistake in ordering, prescribing, dispensing, administering or monitoring (the effect of) a medication.

Medication Ordering System: the system whereby a medical professional hand-writes prescriptions that are sent to, transcribed by and checked by the hospital pharmacist.

Medical record: set of documents to register and store the health data of an individual patient. This will consist of physicians' notes, nurses' notes, prescriptions, orders, laboratory and other test results, and reports of interventions.

Medicinal product: any substance or combination of substances presented for treating or preventing disease in human beings.

Patient safety: the prevention of errors and adverse effects to patients associated with healthcare. While healthcare has become more effective over the years, it has also become more complex, with greater use of new technologies, medicines and treatments. While these bring benefits, they can also increase risks to patient safety.

Prescriber: a healthcare professional authorised (and often licensed) to prescribe a treatment and/or medication, such as a physician, a midwife, a physician assistant and, in specific situations, a nurse.

Prescription[19]: instruction issued by a professional person qualified to do so (written or electronic) that authorises a patient to be issued with a medicinal product or treatment. National policies on over-the-counter and prescription-only medications may differ. In a hospital setting, the physician will prescribe medication for the individual patient and the pharmacist will verify and support the dispensing process.

Primary packaging: the first layer containing the finished product, or the packaging that is in direct contact with the product. In this document, it refers to the packaging of the medicinal product which is in direct contact with the product and is marked with a data carrier either on the packaging or on a label affixed to the packaging.

Single unit dose: (a package that contains) one unit of medication. A single unit dose can also be a single vial or a medicine unit out of its blister pack.

Secondary packaging: the level of packaging that may contain one or more primary packages or a group of primary packages containing a single item. Secondary packaging is the packaging that holds together the individual units of a product. This type of packaging is used to group a certain number of products to create a stock-keeping unit. It facilitates the handling of smaller products by collating them into one pack.

Standards: rules that govern technology, behaviour and interaction. They are an agreed way of doing

[17] https://www.ihe.net
[18] https://www.jointcommissioninternational.org.
[19] also called medication order

things, giving organisations a set of tools with the potential to help them perform better. Standards are different from regulation. Regulation is a rule or directive made and maintained by an authority.

Track-and-trace of medications: a process used to determine a medicinal product's current and past locations. When track-and-trace is correctly implemented, a drug can be tracked throughout the supply chain and traced back up the supply chain upon return or recall. A pharmaceutical track-and-trace system is a logistical technology that enables the tracking and localisation of a medicine throughout the supply chain. In the scope of this document, track-and-trace is limited to the in-hospital environment, from the pharmacy up to the point of administration to the patient.

Unit dose: the ordered amount of a drug in a dosage form prepared for a one-time administration to an individual, indicating the name, strength, lot and/or batch number. A unit dose is the amount of a medication administered to a patient in a single dose.

18. Further reading (to be finalised in next version)

1. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995; 274:29-34.

2. CD-P-PH, pharmaceutical practices and pharmaceutical care (EDQM); https://www.edqm.eu/en/pharmaceutical-practices-and-pharmaceutical-care?p_l_back_url=%2Fen%2Fweb%2Fedqm%2Fsearch%3Fq%3DCDPPH%252FPC%2Bguidance%25E2%2580%2599s%2Bterminology

3. CPOE: Megan Charles, Alex DelVecchio, Brian Eastwood. TechTarget; Health IT; Updated October 2018: https://www.techtarget.com/searchhealthit/definition/computerized-physician-order-entry-CPOE

4. Cap Gemini Consulting: Report by order of Dutch Ministry of Health: 'Barcodering op de primaire verpakking van geneesmiddelen in ziekenhuizen; een kosten-baten analyse', 2017: https://open.overheid.nl/documenten/ronl-archief-752101ad-99a9-444d-8d2c-af9e41491b9a/pdf

5. Warren Connolly, Natasha Rafter, Ronan M Conroy, Cornelia Stuart, Anne Hickey, David J Williams: The Irish National Adverse Event Study-2 (INAES-2): longitudinal trends in adverse event rates in the Irish healthcare system, 2020, https://qualitysafety.bmj.com/content/30/7/547

6. Cummings J, Bush P, Smith D, Matuszewski K (15 December 2005). "Bar-coding medication administration overview and consensus recommendations". American Journal of Health-System Pharmacy. 62(24): 2626–9.doi:10.2146/ajhp050222.PMID 16333061.

7. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32001L0083

8. EAHP on traceability for hospital pharmacist: https://statements.eahp.eu/statements/statement-511 https://statements.eahp.eu/statements/final-statements

9 EDQM: Resolution CM/Res(2020)3: on the implementation of pharmaceutical care for the benefit of patients and health services

10. European Commission; Presentation Patrizia Tosetti, DG Sante: Medicines verification in Europe, what to expect in 2019; https://health.ec.europa.eu/system/files/2016-11/201602_stakeholders_workshop_final_0.pdf

11. European Medicines Verification System (EMVS); European Pack Coding Guidelines, Version 4.0 July 2017: https://emvo-medicines.eu/new/wp-content/uploads/European-Pack-Coding-Guideline-V4_0.pdf

12. Expert Group on Safe Medication Practices. Creation of a better medication safety culture in Europe: Building up safe medication practices. 2006. http://optimiz-sih-circ-med.fr/Documents/Council_of_Europe_Medication_Safety_Report_19-03-2007.pdf

13. Feargal McGroarty, St James's Hospital, Dublin, Ireland, 2011-12: Barcoding on pharmaceutical packaging cuts costs and improves patient safety: https://www.gs1ie.org/download_files/healthcare_files/haemophilia_treatment_traceability_case_studyv2.pdf

14. G-Standaard: the Dutch drug database which is used by all parties in healthcare in the Netherlands. The G-Standaard contains all the products that are dispensed by or used in the pharmacy. It enables an efficient exchange of information between healthcare parties. https://www.z-index.nl/english

15. GS1 Healthcare:
- Antonius Hospital makes safer medication a priority: https://www.gs1.org/industries/healthcare/reference-books-library
- Hospital Israelita Albert Einstein continues its journey to full traceability of pharmaceuticals
- Webinars: https://www.gs1.org/industries/healthcare/hpac/webinars#tab-2018
  - § Richard Price, EAHP, 2014: Bar coding medicines to the single unit administered in hospitals: EAHP's work towards a solution
  - § Thomas de Rijdt, UZ Leuven, Belgium, 2014: The missing link in hospital pharmacy
  - § Pieter Helmons: 2018: Yes we scan! Minimizing medication administration errors through successful change management, the Netherlands
  - § 2019: Bedside Scanning requires cultural change, Copenhagen, Denmark

16. HealthManagement.org, 2015. Heidi Wimmers, Argentina: Why is Drug Traceability Important in a Hospital? https://healthmanagement.org/c/icu/issuearticle/why-is-drug-traceability-important-in-a-hospital

17. HIMSS (Healthcare Information and Management Systems Society), EMRAM stage 7 validation Europe 2022: https://www.himss.org/news/himss22-europe-celebrates-healthcare-systems-validated-emram-stages-6-and-7

18. Hogerwaard M, Stolk M, Dijk L, et al. Implementation of barcode medication administration (BMCA) technology on infusion pumps in the operating rooms. BMJ Open Quality 2023; Implementation of barcode medication administration (BMCA) technology on infusion pumps in the operating rooms. BMJ Open Quality 2023;12:e002023. doi:10.1136/bmjoq-2022-002023..

19. ICT&Health: barcodes on medication enhances patient safety, 2017: https://icthealth.nl/nieuws/barcodes-op-medicijnverpakking-vergroot-patientveiligheid/

20. Institute of Medicine. Quality Chasm Series. Preventing Medication Errors. Washington DC: National Academy Press; 2007

21. Integrating the Healthcare Enterprise (IHE):
- Hospital Medication Workflow. 2019. https://wiki.ihe.net/index.php/Hospital_Medication_Workflow
- IHE Pharmacy Profiles: https://www/ihe.net/ihe_domains/pharmacy
- https://www.ihe.net/uploadedFiles/Documents/Pharmacy/IHE_Pharm_Suppl_MMA.pdf

2019
- Mobile Medication Administration: https://wiki.ihe.net/index.php/Mobile_Medication_Administration
- Uniform Barcode Processing: https://wiki.ihe.net/index.php/Uniform_Barcode_Processing

22. IHE/Nictiz article: interoperability: https://nictiz.nl/app/uploads/2022/10/ICThealth_nr5_2022_60-61.pdf

23. Interoperability of track and trace systems: key to public health protection | European Medicines Agency; News 06/08/2021

24. McKinsey&Company: Strength in Unity, the promise of global standards in healthcare, 2012, https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/operations/pdfs/ops_%20%20mck%20white%20paper%20global%20standards%20vf.pdf

25. National Health Service, NHS, UK: web based information:
- NHS digital:
  - https://digital.nhs.uk
  - https://digital.nhs.uk/services/digital-and-interoperable-medicines/resources-for-health-and-care-services/other-resources/strategic-drivers
- Scan4Safety: https://www.scan4safety.nhs.uk/index.html

26 Nictiz article: medical data exchange EU-countries: https://nictiz.nl/app/uploads/2022/10/ICThealth_nr5_2022_62-63.pdf

27. Nursing, 2011: Cardex-medication: https://www.nursing.nl/blog/medicatie-verstrekken-hoe-doe-je-dat-veilig-op-een-zuigelingenafdeling-nurs006669w/

28. Official Journal of the European Union: COMMISSION DELEGATED REGULATION (EU) 2016/161 of 2 October 2015; supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use: https://health.ec.europa.eu/system/files/2016-11/reg_2016_161_en_0.pdf via https://health.ec.europa.eu/medicinal-products/falsified-medicines_en

29. Peter Lachman, Els van der Wilden, IJQHC Communications, 2021, 1(1), 1–3; DOI: https://doi.org/10.1093/ijcoms/lyab014. Use of barcode technology can make a difference to patient safety in the post-COVID era

30. Pieter Helmons: Medication safety through information technology: a focus on medication prescribing and administering. 2014. Dissertation. Rijksuniversiteit Groningen: https://www.rug.nl/about-ug/latest-news/news/archief2014/promoties/promotie-p.j.-helmons_medication-safety-through-information-technology.-a-focus-on-medication-pr or https://research.rug.nl/files/3668356/Helmons_thesis.pdf https://pure.rug.nl/ws/portalfiles/portal/3668356/Helmons_thesis.pdf

31. Pharmaceutical Track&Trace system, Turkey: https://www.drugtrackandtrace.com/drug-track-and-trace-system/

32. Website: GS1 Nederland:
- Barcoding to uniquely identify medications: https://www.gs1.nl/nieuws-en-events/nieuws/2017/nvza-nu-doorpakken-met-uniforme-toedieningsregistratie/

33. WHO: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

34. WHO: pharmaceutical track&trace system: https://www.drugtrackandtrace.com/drug-track-and-trace-system/concepts/

34. WHO: Irish case on vaccine delivery: https://www.who.int/ireland/news/item/09-09-2022-ireland-tracks-its-way-to-covid-19-vaccine-delivery-success

35. W. van der Veen, dissertation: Information technology and medication safety, Groningen Graduate School of Science and Engineering (GSSE), the University of Groningen, the Netherlands, 2018; https://www.gildeprint.nl/flippingbook/Information%20Technology%20and%20Medication%20Safety/20/index.html

36. World Hospital and Health Services: International Hospital Federation Official Journal 2018 Volume 54 Number 4: several articles on barcoding, medication safety and traceability: https://region1.healthresearch.ph/index.php/research-news/145-r1hrdc-international-hospital-federation-official-journal-2018-volume-54-number-4

37. Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom: Consultation on point-of-care manufacturing: https://www.gov.uk/government/consultations/point-of-care-consultation/consultation-on-point-of-care-manufacturing

38. Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom: https://www.gov.uk/government/news/uk-to-introduce-first-of-its-kind-framework-to-make-it-easier-to-manufacture-innovative-medicines-at-the-point-of-care